DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 5, 2015

Spacelabs Healthcare
% Thomas Kroenke, Principal Consultant
Speed To Market, Inc.
PO Box 3018
Nederland, Colorado 80466

Re: K150329
Trade/Device Name: *élance* Vital Signs Monitor and *élance* Central Station
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: October 1, 2015
Received: October 6, 2015

Dear Thomas Kroenke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

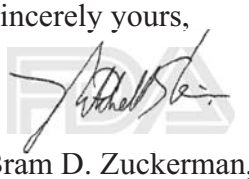
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K150329

Device Name: *élance* Vital Signs Monitor and *élance* Central Station

Indications For Use: The Spacelabs *élance* Vital Signs Monitor and *élance* Central Station is indicated for use in patient populations for:

- Adult
- Pediatric (1 year old and above)

The Spacelabs *élance* Vital Signs Monitor and *élance* Central Station facilitates the monitoring of:

- ECG with arrhythmia detection
- Respiration
- Non-invasive blood pressures
- Invasive blood pressures
- Body temperature
- Functional arterial oxygen saturation, and
- End tidal CO2.

The Spacelabs *élance* Vital Signs Monitor and *élance* Central Station is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)

# *510(k) Summary*

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|---|---|
| ***Submission Date:*** | 01 October 2015 |
| ***Submitter:*** | Spacelabs Healthcare<br>35301 SE Center St<br>Snoqualmie, WA 98065 |
| ***Submitter Contact:*** | Mr. Al Van Houdt<br>Spacelabs Healthcare<br>Phone: +1 (425) 363- 5970<br>Fax: +1 (425) 363-5762<br>Email: al.vanhoudt@spacelabs.com |
| ***Application Correspondent:*** | Thomas Kroenke<br>Speed To Market, Inc.<br>PO Box 3018<br>Nederland, CO 80466 USA<br>tkroenke@speedtomarket.net<br>303 956 4232 |
| ***Manufacturing Site:*** | Spacelabs Healthcare<br>35301 SE Center St<br>Snoqualmie, WA 98065 |
| ***Trade Name:*** | *élance* Vital Signs Monitor and *élance* Central Station |
| ***Common Name:*** | Patient Physiological Monitor (with arrhythmia detection or alarms) |
| ***Classification Name:*** | Patient Physiological Monitor (with arrhythmia detection or alarms) |
| ***Primary Classification Regulation:*** | 21 CFR §870.1025 |
| ***Primary Product Code:*** | MHX |

***Substantially Equivalent Devices:***

| *New Spacelabs Model* | *Predicate 510(k) Number* | *Predicate Manufacturer / Model* |
|---|---|---|
| Spacelabs Healthcare *élance* Vital Signs Monitor and *élance* Central Station | K093501 | Spacelabs Healthcare *élance* Vital Signs Monitor and *élance* Central Station |
| | K033296 | Masimo Corporation Masimo SET® Rad-5 Pulse Oximeter |
| | K012891 | Nellcor Puritan Bennett Incorporated OxiMAX Pulse Oximetry System with N-595 Pulse Oximeter and OxiMAX Sensors and Cables |

# *510(k) Summary*

***Device Description:***

The Spacelabs Healthcare (Spacelabs) *élance* Vital Signs Monitor is a family of portable patient monitors intended to be used by clinicians and medical qualified personnel for monitoring ECG with arrhythmia detection, respiration, NIBP, temperature, $SPO_2$, invasive blood pressure and $EtCO_2$. Models within the Spacelabs *élance* family come in two different sized viewing areas (10.2" and 12.1"), two different housing colors (white and black) and offer selected monitoring features.

The Spacelabs *élance* Central Station software package is available for use with a customer acquired computer based on specifications provided by Spacelabs. This package allows monitoring of the *élance* Vital Signs Monitor at a central workstation.

***Intended Use:***

The Spacelabs *élance* Vital Signs Monitor and *élance* Central Station is indicated for use in patient populations for:

- Adult
- Pediatric (1 year old and above)

The Spacelabs *élance* Vital Signs Monitor and *élance* Central Station facilitates the monitoring of:

- ECG with arrhythmia detection
- Respiration
- Non-invasive blood pressures
- Invasive blood pressures
- Body temperature
- Functional arterial oxygen saturation, and
- End tidal $CO_2$.

The Spacelabs *élance* Vital Signs Monitor and *élance* Central Station is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.

# *510(k) Summary*

***Technology Comparison:***

The Spacelabs Spacelabs *élance* Vital Signs Monitor and *élance* Central Station employs the same technological characteristics as the predicate device.

| ***Characteristic*** | ***Predicate Device*** | ***Proposed Device*** |
|---|---|---|
| *Parameters* | ECG with arrhythmia detection<br>Respiration<br>Non-invasive blood pressure<br>Invasive blood pressure<br>Body temperature<br>Functional arterial oxygen saturation, and<br>End tidal $CO_2$. | Same |
| *Display Type* | LCD | Same |
| *Display Sizes* | 10.2" and 12.1" | Same |
| *VSM Variants* | 5, 5i, 5c, 5 elite, 5i elite, 5c elite<br>7, 7i, 7c, 7 elite, 7i elite, 7c elite | Same |
| *Additional Options* | - | 93300-M, Masimo SpO2<br>93300-N, Nellcor SpO2<br>93300-A: Arrhythmia<br>93300-S: ST Segment Analysis |

***Summary of Performance Testing:***

*Software*

The *élance* VSM and *élance* CS contain MAJOR level of concern software. Software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software information is provided in accordance with

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99;*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02; and*
- *FDA guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, 14 Jun 13*

Test results indicated that the *élance* VSM and *élance* CS software comply with predetermined specification.

# *510(k) Summary*

*Electrical Safety*

The *élance* VSM was tested for patient safety in accordance with:

- *IEC 60601-1:1988, Am1: 1991, Am2: 1995, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

Test results indicated that the *élance* VSM complies with the applicable standards.

*Electromagnetic Compatibility*

The *élance* VSM was tested for EMC in accordance with:

- *IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*

Test results indicated that the *élance* VSM complies with the applicable standards.

*Performance Testing – Bench*

The *élance* VSM was tested for parameter performance in accordance with:

- *ANSI/AAMI EC57: 1998/(R) 2003, Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms;*
- *ANSI/AAMI SP10: 2002, Am1: 2003, Manual, electronic, or automated sphygmomanometers;*
- *EN 12470-4: 2009, Clinical thermometers – Part 4: Performance of electrical thermometers for continuous measurement;*
- *EN 60601-1-6: 2010, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability;*
- *EN 60601-1-8 2007, Am1: 2013, AC: 2014, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems;*
- *EN 62366: 2008, Medical devices - Application of usability engineering to medical devices;*
- *IEC 60601-2-27: 2005, Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment;*

# *510(k) Summary*

*Performance Testing – Bench (continued)*

- *IEC 60601-2-30: 1999, Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment;*
- *IEC 60601-2-34: 2000, Medical electrical equipment – Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment;*
- *IEC 60601-2-49: 2011, Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment;*
- *ISO 80601-2-55: 2011, Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors; and*
- *ISO 80601-2-61: 2011, Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.*

The *élance* CS was tested for parameter performance in accordance with:

- *EN 60601-1-6: 2010, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability;*
- *EN 60601-1-8 2007, Am1: 2013, AC: 2014, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems;*
- *EN 62366: 2008, Medical devices - Application of usability engineering to medical devices;*
- Test results indicated that the *élance* VSM and *élance* CS comply with these Standards. Additionally, the *élance* VSM and *élance* CS were tested in accordance with internal requirements and procedures, and test results indicated that the devices comply with the predetermined requirements.

***Conclusion***

Verification and validation activities were conducted to establish the performance and safety characteristics of the *élance* VSM and *élance* CS. The results of these activities demonstrate that the *élance* VSM and *élance* CS are as safe, as effective, and perform as well as or better than the predicate devices. Therefore, the *élance* VSM and *élance* CS are considered substantially equivalent to the predicate devices.